NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BECTON, DICKINSON AND COMPANY,	
Plaintiff,	**Civil Action No. 10-4371 (ES)**
v.	**OPINION**
INSULET CORPORATION,	**(Filed Under Temporary Seal)**
Defendant.	

SALAS, DISTRICT JUDGE

I. Introduction

Before the Court is the parties' request for claim construction of certain disputed terms in this patent infringement action. The Court held a *Markman* hearing on December 10, 2012. This Opinion sets forth the Court's construction of the disputed claim terms.

II. Background

Plaintiff Becton, Dickinson and Company ("Plaintiff" or "BD") brought this action against Insulet Corporation ("Defendant" or "Insulet") for infringement of the following three patents: U.S. Patent Nos. 5,536,249 C1 (the "'249 patent"); 5,925,021 (the "'021 patent"); and 5,957,895 (the "'895 patent"). (D.E. No. 38, BD's Opening *Markman* Brief ("BD Open. Br.") at 1; *see also* D.E. No. 1, Complaint ¶ 1). BD alleges that Insulet's diabetes management systems, including its Omnipod® Insulin Management System, infringe these three patents under 35 U.S.C. § 271(a), (b), and/or (c). (Complaint ¶¶ 14, 22, 28).

Briefly, the ’249 patent discloses certain medical injection devices. (’249 Patent at 1:6-13; 2:43-48). According to embodiments of the ’249 patent, the “medical injection device, such as a pen-type injector or the like, has a processor coupled to the injector that records the date, the time, and the amount of each injection.” (*Id.* at 2:43-48). And, in “particular embodiments,” the medical device “includes a pen-type injector that is also coupled with a blood characteristic monitor to analyze characteristics of the blood.” (*Id.* at 3:1-4). Also in “particular embodiments,” the “processor determines a value equal to the dosage of the medication to be injected by the medication injector” and “also determines blood characteristics from a blood sample analyzed by the blood characteristic monitor.” (*Id.* at 3:7-15).

In this action, BD asserts independent Claims 9, 33, and 48, as well as various dependent claims from the ’249 patent. (BD Open. Br. at 3).[1] By way of example, Claim 9 is as follows:

> 9. A medical device, comprising:
>
> a medical injector for injecting a dosage of a medication;
>
> a blood characteristic monitor for analyzing a *non-perfusate* blood sample;
>
> a processor coupled to the medication injector and the blood characteristic monitor, wherein the processor determines a value equal to the dosage of the medication to be injected by the medication injector, and wherein the processor determines blood characteristics from the *non-perfusate* blood sample analyzed by the blood characteristic monitor.

The ’021 patent claims priority to the ’249 patent and includes the ’249 patent disclosure while providing additional disclosures. (BD Open. Br. at 4). In this action, BD asserts

[1] Claims 9, 33, and 48 were amended upon reexamination at the PTO. (*See* ’249 Patent Reexamination Certificate; Pl. Open. Br. at 3-4). To the extent that this Opinion reproduces claim language for any claims that were amended upon reexamination (namely, Claims 9, 33, and 48), the Opinion does so by including the textual modifications that are reflected in the reexamination certificate.

independent Claims 1 and 11, as well as various dependent claims, against Insulet. (*Id.*). Claim 1, for example, is as follows:

> 1. A medical monitor, comprising:
>
> a portable housing;
>
> a characteristic monitor contained in the portable housing for analyzing a characteristic sample;
>
> a processor coupled to the characteristic monitor, wherein the processor includes determining means for determining characteristics based on the analyzed characteristic sample from the characteristic monitor; and
>
> a data port coupled to the processor, wherein the data port includes transferring means for transferring data and program instructions from a medication delivery device to the processor,
>
> wherein the processor includes means for using the characteristics and the data from the medication delivery device to compare the characteristics and data to determine if the medical regimen is correct and whether modifications to the medical regimen are required.

Finally, the ’895 patent “relates to a low-profile automatic injection device that can be worn inconspicuously under the clothing of a patient to allow a liquid theraputic [sic] preparation (such as insulin) to be administered over an extended period of time, and that incorporates a self-emptying reservoir to eliminate the need for a pump or other type of discharge device.” (’895 Patent at 1:9-15). BD is asserting independent Claim 14 and dependent Claim 16 of the ’895 patent. (BD Open. Br. at 6). Independent Claim 14 is as follows:

> 14. A device for delivering a liquid theraputic [sic] preparation into the body of a patient by injection into or through the skin, comprising:
>
> a low-profile housing having a bottom surface adapted to be brought into contact with the skin of a patient, said bottom surface having a needle aperture therein, said housing being sufficiently

> low in height to allow said device to be worn inconspicuously under the clothing of the patent [sic];
>
> a reservoir disposed within said housing for containing a liquid theraputic [sic] preparation;
>
> an injection needle disposed generally horizontally in said housing and adapted to communicate with said reservoir, said injection needle having a bent injection end adapted to project through said needle aperture; and
>
> a movable needle carrier disposed in said housing for carrying said injection needle and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier;
>
> wherein said needle carrier and said injection needle are disposed in a side-by-side relationship with said reservoir in said housing in order to minimize the height of said housing above said bottom surface.

As detailed below, the parties have asked the Court to construe several terms from the claims of these three patents.

III. Legal Standard

A. General Principles of Claim Construction

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted). Claim construction is a matter of law to be determined solely by the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996).

"[T]he words of a claim are generally given their ordinary and customary meaning" which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13 (internal quotations omitted). To determine the ordinary and customary meaning of disputed claim language that has a "particular

meaning in a field of art," the court must look to "those sources available to the public that show what a person of skill in the art would have understood [the] disputed claim language to mean." *Id.* at 1314 (internal quotations omitted).

Thus, the court must "look to the claim language, the specification, the prosecution history, and any relevant extrinsic evidence." *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1368 (Fed. Cir. 2012); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. These sources . . . include both intrinsic evidence (*e.g.*, the patent specification and file history) and extrinsic evidence (*e.g.*, expert testimony).").

With respect to intrinsic evidence, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. Indeed, "the context in which a term is used in the asserted claim can be highly instructive." *Id.* Similarly, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.*

Importantly, the specification "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics*, 90 F.3d at 1582). "[T]he specification may reveal a special definition given to a claim term by the patentee" or "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Phillips*, 415 F.3d at 1316. Indeed, "the specification necessarily informs the proper construction of the claims" and it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1316-17.

Notably, however, the court may "not read limitations from the specification into claims." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). Specifically, the Federal Circuit has "repeatedly warned against confining the claims to . . . embodiments" described in the specification. *Phillips*, 415 F.3d at 1323.

The court must also consider the patent's prosecution history—"the complete record of the proceedings before the PTO . . . includ[ing] the prior art cited during the examination of the patent." *Id.* at 1317. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* Although the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes," it can nevertheless "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In sum, "[c]laim terms are given their ordinary and customary meaning—the meaning that they would have to a person of ordinary skill in the art in light of the specification and prosecution history at the time of the invention." *Woods v. DeAngelo Marine Exhaust, Inc.*, 692 F.3d 1272, 1283 (Fed. Cir. 2012). And "[c]laim terms are properly construed to include limitations not otherwise inherent in the term only when a patentee sets out a definition and acts as his own lexicographer, or when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Id.* (internal quotations omitted); *see also Aventis Pharm. Inc. v. Amino Chems. Ltd.*, No. 11-1335, 2013 WL 2151105, at *6 (Fed. Cir. May 20, 2013) ("The written description and other parts of the specification, for example, may shed contextual light on the plain and ordinary meaning; however, they cannot be used to narrow a

claim term to deviate from the plain and ordinary meaning unless the inventor acted as his own lexicographer or intentionally disclaimed or disavowed claim scope.").

Finally, the court may also rely on extrinsic evidence—"all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995)). But, extrinsic evidence "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1319.

IV. Construction of Disputed Claim Terms

A. Disputed Claim Terms in the '249 Patent

1. "A medical device"

The parties dispute the meaning of this term from independent Claim 9 of the '249 patent. The parties agree that substantially the same term appears in independent Claims 33 and 48. (BD Open. Br. at 8 n.2; D.E. No. 36, Insulet's Opening *Markman* Brief ("Insulet Open. Br.") at 7). These claims appear as follows in the '249 patent reexamination certificate (with bold typeface for the disputed claim language):

> 9. **A medical device**, comprising:
>
> a medical injector for injecting a dosage of a medication;
>
> a blood characteristic monitor for analyzing a *non-perfusate* blood sample;
>
> a processor coupled to the medication injector and the blood characteristic monitor, wherein the processor determines a value equal to the dosage of the medication to be injected by the medication injector, and wherein the processor determines blood characteristics from the *non-perfusate* blood sample analyzed by the blood characteristic monitor.

33. A portable **medical device** to maintain and monitor a condition of an individual's body, the device comprising:

an injector for injecting a dosage of an injectable substance into the individual's body;

a characteristic monitor for analyzing a *non-perfusate* fluid sample consisting of **[**saliva, urine or**]** blood removed from the individual's body;

a processor coupled to the injector and the characteristic monitor, wherein the processor determines a value equal to the dosage of the injectable substance to be injected by the injector into the individual's body, and wherein the processor determines sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor.

48. A method of maintaining and monitoring a condition of an individual's body with a portable **medical device**, the method comprising the steps of:

determining a value equal to a dosage of an injectable substance to be injected into the individual's body using a processor in the **medical device**;

injecting a dosage of **[**a**]** the injectable substance into the individual's body using an injector in the **medical device**;

removing a *non-perfusate* fluid sample consisting of **[**saliva, urine or**]** blood removed from the individuals body;

analyzing **[**a**]** *the non-perfusate* sample with a characteristic monitor in the **medical device**;

determining sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor with the processor in the **medical device**.

BD's Proposed Construction: "One or more integrated components used for a medical purpose"

Insulet's Proposed Construction: "A single, self-contained structure that has the components in the remainder of the claim"

Court's Construction: "One or more integrated components used for a medical purpose"

BD argues that "the claim language does not limit [C]laims 9, 33, or 48 to a single housing containing all of the claimed components." (BD Open. Br. at 8). BD observes that, in contrast, "the inventors expressly limited other claims of the '249 patent and related patents to a particular device structure" such as Claim 1 of the '249 patent, which "expressly recites that all claim components of the 'device' must reside 'in a single handheld housing.'" (*Id.* at 8-9 (quoting Claim 1 of the '249 patent)). BD contends that the '249 patent specification also supports its proposal because certain disclosed embodiments do *not* use a single housing. (*Id.* at 9-10). BD further argues that, even if all the disclosed embodiments use a single housing, this is insufficient to "limit the more broadly claimed 'device.'" (*Id.* at 10). BD also cites prosecution history that allegedly "confirms that the applicant and the patent examiner intended to limit only [C]laim 1—and not asserted [C]laims 9, 33, and 48—to a single housing." (*Id.* at 10-11). Finally, BD relies on the FDA's definition of "device" as extrinsic evidence to argue that the industry understood the disputed claim language to include "a multi-component product" and that Insulet "sought approval of its multi-component, multi-housing product at issue here, repeatedly referring to it as a 'device' in its FDA submissions." (*Id.* at 11-12).

Insulet argues, however, that the '249 patent explains that a "disadvantage of the prior art is that a patient had to use a blood glucose meter that was physically separate from the patient's insulin injector" and that an advantage of the invention is that the device is "a single, all-in-one device." (Insulet Open. Br. at 8-9 (emphasizing "single, all-in-one device" language from the '249 patent specification)). Insulet therefore contends that the "relevant disclosures of the '249 patent are all directed to a single, 'all-in-one' structure" and that "[e]very relevant figure depicts a single physical structure." (*Id.* at 13).

Insulet also argues that, during prosecution, "the inventors repeatedly characterized a prior art 'system' that was a set of 'integrated components used for a medical purpose' . . . as different from the single device described in their applications." (*Id.*). Specifically, Insulet cites the following aspects of the prosecution history: (1) the applicants' preliminary amendment and election of invention where they explain that Claims 9, 33, and 48 cover the combined device shown in Figures 14-18 of the '249 patent; (2) the related '021 patent—which issued from an application that was the last in a series that began with the application for the '249 patent—that claims a "medication delivery device" that is in a separate housing from a "medical monitor"; (3) in the prosecution of a related application that led to U.S. Patent No. 5,593,390, the applicants' characterization of the relevant embodiments of their invention as a single structure and distinguished an asserted prior art reference—referred to by the parties as the "Leslie reference"—based on this feature; and (4) in the prosecution of a related application that led to U.S. Patent No. 5,728,074, the applicants' characterization of the Leslie reference in a way that would be encompassed by BD's proposal here. (*Id.* at 10-13).

"Claim terms are properly construed to include limitations not otherwise inherent in the term only when a patentee sets out a definition and acts as his own lexicographer, or when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Woods*, 692 F.3d at 1283 (internal quotations omitted). Here, the patentee has not provided lexicography or disavowal that would limit the scope of the disputed language to "a single, self-contained structure"—or, in other words, a single housing.

Indeed, rather than limiting the scope of "medical device" to "a single, self-contained structure," the '249 patent envisions an embodiment in which a medical device is a pen-type injector with a *physically separate* watch monitor that has a blood characteristic monitor.

Specifically, the specification explains that, in particular embodiments, "*a medical device* includes a pen-type injector that is also coupled with a blood characteristic monitor . . . ." ('249 Patent at 3:1-3 (emphasis added)). Importantly, this blood characteristic monitor can reside in a watch monitor that is physically separate from the pen-type injector. (*See id.* at 3:46-48 ("According to a further embodiment of the present invention, a watch monitor includes a blood characteristic monitor . . . ."); 13:52-54 ("The wrist watch **304** is secured to the user's wrist by a pair of watch straps **312**."); 16:23-25 ("In alternative embodiments, the watch monitor **300** can be used with a pen-type injector **10** . . . ."). Thus, the Court is not convinced that the specification limits the scope of "medical device" to "a single, self-contained structure."

To be sure, the Court is not persuaded otherwise by Insulet's observation that "each figure that depicts the combined injector/blood glucose monitor shows a single physical structure that includes both a medication injector and a blood glucose monitor." (Insulet Open. Br. at 9). This is insufficient to limit "medical device." *See Thorner*, 669 F.3d at 1365-66 ("It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to redefine the term. . . . Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal. . . . It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation.") (internal quotations omitted).

Furthermore, the Court is not convinced that the use of the "single, all-in-one device" language in the written description limits "medical device" to a "single, self-contained structure." As BD suggested during the *Markman* hearing, the issue raised by the parties' dispute is the scope of the "single, all-in-one device" language. (*See* Tr. at 41:3-10). To that extent, the '249

patent specification does not explicitly or implicitly preclude the "all-in-one device" from having components that reside in two housings. Instead, the specification explains that a "*single, all-in-one device* provides medication injection, blood characteristic monitoring, and record keeping," but (as discussed above) describes an embodiment in which a "watch monitor **300** can be used with a pen-type injector **10**" and the "blood characteristic monitor **302** is contained with the housing of the wrist watch **304**." ('249 Patent at 6:5-7; 13:38-39; 16:23-24 (emphasis added)).[2] Additionally, that independent Claim 1 explicitly requires "a single hand held housing" buttresses the Court's conclusion that the disputed claim language from independent Claims 9, 33, and 48 should not be limited as Insulet proposes.

Finally, the Court is not convinced that the patentee disavowed the full scope of the disputed claim language during prosecution of this, or any related application, to limit "medical device" to a "single, self-contained structure." The applicants' response to the restriction requirement does not amount to a clear and unmistakable disavowal of claim scope. Rather, the applicants' statement that Claims 9, 33, and 48 "are generic to the species disclosed in Figs. 14-18" suggests that these claims *cover* the embodiments disclosed in these figures, not that the claims are *limited* to these embodiments. (*See* Ex. 5 to Insulet Open. Br. at 8).

Furthermore, the Court does not find that the applicants' statements during the prosecution of the related applications, which led to U.S. Patent Nos. 5,593,390 and 5,728,074, warrant accepting Insulet's proposal because, in those applications, the applicants specifically added single housing claim language. (*See* Ex. 11 to Insulet Open. Br. at 2-4 ('390 Patent); Ex. 14 to Insulet Open. Br. at 2-3 ('074 Patent)). The Court is therefore not persuaded that the

[2] The written description explains that a "single, all-in-one device" permits a user to *not* "carry a large number and variety of items" such as "a separate medication vial, a separate medication injector, a separate blood characteristic monitor and a separate log book." ('249 Patent at 6:9-12). To be sure, this rationale for the claimed invention does not preempt a device that has two physically separate components, such as one that has a pen-type injector in one housing and a watch monitor in another housing. Indeed, a device like this would still reduce the number and variety of items consistent with the purported rationale for the invention.

applicants' statements in those prosecutions limit the disputed claim language in the '249 patent where the single housing limitation is absent from Claims 9, 33, and 48. *See Ventana Med. Sys., Inc. v. BioGenex Labs., Inc.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006) ("[T]he doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language."). Similarly, the Court is not persuaded that the claim language in the related '021 patent (i.e., claiming a "medication delivery device" that is in a separate housing from a "medical monitor") supersedes the analysis above concerning the claim language and specification of the '249 patent. *See Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1331 (Fed. Cir. 2012) ("The prosecution history can offer insight into the meaning of a particular claim term, but the claim language and the specification generally carry greater weight.") (internal quotations & textual modifications omitted).

In sum, BD's proposal is consistent with the intrinsic evidence and the Court therefore construes "medical device" to mean "one or more integrated components used for a medical purpose."

2. "injector for injecting"[3]

The parties dispute the meaning of this term from independent Claim 9 of the '249 patent. The parties agree that substantially the same term appears in independent Claims 33 and 48. (BD Open. Br. at 12 n.3; D.E. No. 50, Insulet's Responsive *Markman* Brief ("Insulet Resp. Br.") at 6). These claims are again provided below (with bold typeface for the disputed claim language at issue):

9. A medical device, comprising:

[3] The Court notes that the parties initially proposed competing constructions for the term "injector for injecting." (BD Open. Br. at 12; Insulet Open. Br. at 13). In its responsive briefing, however, Insulet provided arguments for construction of the term "an injector for injecting a dosage of medication," (Insulet Resp. Br. at 6), while BD continued to dispute the scope of "injector for injecting." This difference, however, does not seem material as the Court considers all the claim language for its analysis. *See Phillips*, 415 F.3d at 1314.

a medical **injector for injecting** a dosage of a medication;

a blood characteristic monitor for analyzing a *non-perfusate* blood sample;

a processor coupled to the medication injector and the blood characteristic monitor, wherein the processor determines a value equal to the dosage of the medication to be injected by the medication injector, and wherein the processor determines blood characteristics from the *non-perfusate* blood sample analyzed by the blood characteristic monitor.

33. A portable medical device to maintain and monitor a condition of an individual's body, the device comprising:

an **injector for injecting** a dosage of an injectable substance into the individual’s body;

a characteristic monitor for analyzing a *non-perfusate* fluid sample consisting of [saliva, urine or] blood removed from the individual’s body;

a processor coupled to the injector and the characteristic monitor, wherein the processor determines a value equal to the dosage of the injectable substance to be injected by the injector into the individual’s body, and wherein the processor determines sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor.

48. A method of maintaining and monitoring a condition of an individual’s body with a portable medical device, the method comprising the steps of:

determining a value equal to a dosage of an injectable substance to be injected into the individual’s body using a processor in the medical device;

injecting a dosage of [a] the injectable substance into the individual’s body **using an injector** in the medical device;

removing a *non-perfusate* fluid sample consisting of [saliva, urine or] blood removed from the individuals body;

analyzing [a] *the non-perfusate* sample with a characteristic monitor in the medical device;

> determining sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor with the processor in the medical device.

BD's Proposed Construction: "A component to infuse from outside a body to inside a body"

Insulet's Proposed Construction: "A device that is inserted into a patient, delivers a single dose of medication, and is then withdrawn"

Court's Construction: "A device that delivers a single dose at a time of a medication or injectable substance from outside a body to inside a body"

BD argues that nothing in the claim language limits an "injector" to a component that is physically inserted into a patient's body or to delivering a single dose. (BD Open. Br. at 12, 13). Citing the specification's disclosure of "jet injectors" and its own expert's testimony about "jet injectors," BD contends that "the specification contemplates an injector that infuses medication without inserting any structure, such as a needle, into the patient's body." (*Id.* at 12-13). BD also argues that Insulet improperly imports limitations from the specification by proposing that the injector provides only one dose before withdrawal. (*Id.* at 13). BD asserts that, although the specification includes injector embodiments that deliver only a single dose prior to withdrawal, it is the claim language that governs. (*Id.*). Finally, BD points to Insulet's documents relating to Insulet's infusion device, which allegedly suggest that delivery of multiple doses can still constitute "injecting." (*Id.* at 14). BD argues that Insulet "cannot ignore its statements showing how a skilled artisan describes its product." (D.E. No. 51, BD's Responsive *Markman* Brief ("BD Resp. Br.") at 5).

Insulet contends, however, that its proposal "conforms to the description of the injection device of the '249 patent." (Insulet Open. Br. at 14). Insulet asserts that the device "delivers a specific dosage of medication on a single, discrete occasion." (Insulet Resp. Br. at 6). It explains that the '249 patent "discloses only a pen-type injection device" that involves selection

of an injection site, pushing the needle under the skin, delivery of a single dose of a medication, and withdrawal of the needle. (Insulet Open. Br. at 14 (citing '249 Patent at 8:66-9:30 & 13:25-30)). And Insulet argues that the '249 patent "does not disclose, and does not claim, a device that is attached to the patient for a material period of time" that "slowly but continuously delivers medication," which would describe an "infusion." (*Id.*).

In addition, Insulet notes that the applicants distinguished the Leslie reference during the prosecution of the '249 patent on the grounds that the Leslie reference "discloses a device that uses an electric motor to infuse a specified amount of medication over a period of time" and asserted that the medication injector is "not disclosed, taught or suggested by the Leslie et al. reference." (Insulet Open. Br. at 15 (quoting Ex. 8 to Insulet Open. Br. at 2-3)). Insulet also notes that, in the prosecution of a related application that led to U.S. Patent No. 5,728,074, the applicants similarly distinguished the Leslie reference by arguing that the Leslie reference "describes an infusion pump that is *fundamentally different* from the recited injection device" and that this reference "does not disclose, teach or suggest an injector that only contacts the patient's body when an injection is administered as recited in the claims." (*Id.* (quoting Ex. 14 to Insulet Open. Br. at 6) (emphasis added by Insulet)). And, in the prosecution of another related application that led to U.S. Patent No. 5,593,390, Insulet contends that the applicants distinguished a reference referred to as the "Rogoff reference" by stating that this reference "only describes the use of pumps that continually supply insulin . . . in response to electrical signals." (*Id.* at 16 (quoting Ex. 11 to Insulet Open. Br. at 8)). Thus, Insulet asserts that "the applicants repeatedly distinguished their single injection device from 'a component to infuse' medication into a patient over a sustained period of time." (*Id.*).

The Court rejects the "infuse" portion of BD's proposal. BD simply fails to identify anything from the intrinsic evidence suggesting that the disputed claim language means to "infuse" or that "infuse" somehow equates to "inject." (*See* BD Open. Br. at 12-14; BD Resp. Br. at 4-7). To be sure, the Court is not persuaded that, because Insulet uses "injecting" terminology when describing its infusion product, the "injector for injecting" claim language must mean "infuse." *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1331 (Fed. Cir. 2006) ("This court . . . repeats its rule that claims may not be construed with reference to the accused device. . . . [T]hat rule posits that a court may not use the accused product or process as a form of extrinsic evidence to supply limitations for patent claim language. . . . [I]t forbids biasing the claim construction process to exclude or include specific features of the accused product or process.") (internal quotations & citations omitted); *see also Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1362 (Fed. Cir. 2013) ("Unless the inventor intended a term to cover more than the ordinary and customary meaning *revealed by the context of the intrinsic record*, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source.") (emphasis in original).[4]

Instead, the Court finds that the disputed claim language is limited to delivering a single dose at a time of a medication or injectable substance. Claims 9, 33, and 48 have "a dosage" language. Although "a" generally means "one or more," the Court must read this limitation "in light of the claim and specification to discern its meaning." *Harari v. Lee*, 656 F.3d 1331, 1341

[4] The Court notes that Insulet also relies on testimony by the inventors of the '895 patent to argue that BD's proposal is improper because BD's proposal would encompass infusion devices, which are different from the claimed injector. (D.E. No. 74, Insulet's Supplemental Markman Brief ("Insulet Supp. Br.") at 7-10). Because the Court rejects the "infuse" portion of BD's proposal based on the intrinsic evidence, the Court need not address Insulet's arguments relating to testimony by the inventors of the '895 patent. *See Vitronics*, 90 F.3d at 1583 ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.").

(Fed. Cir. 2011). And nothing in the claims or specification suggests that more than one dose can be delivered at a time using the claimed injector. Rather, the claims and specification contemplate a single injection at a time. (*See, e.g.*, '249 Patent at 5:63-65 ("*To inject a dose* of medication, the user inserts the needle under the skin and depresses the dosage once [sic] knob once as far as it will depress."); 8:66 ("To give *an injection* with the pen-type injector . . . ."); 9:3-7 ("In preferred embodiments . . . the microprocessor **32** displays the time and the amount of the last injection on the display . . . to remind the user of the last injection event."); 9:24-29 ("After the dosage is selected, the user chooses an injection site, pushes the disposable needle **28** under the skin and depresses the actuator knob **12** down as far as it will go. The actuator knob **12** automatically locks in the depressed position when the actuator is depressed completely and the injection is completed."); 9:29-30 ("When the actuator knob **12** is depressed, the microprocessor **32** stores the injection event . . . .") (emphasis added)).

The Court recognizes the general prohibition of limiting claim language to disclosed embodiments, but finds that this is a situation where the claims and disclosed embodiments are coextensive. *See Phillips*, 415 F.3d at 1323 (recognizing that, in certain situations, "it will become clear . . . [that] the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive"); *see also Saffran v. Johnson & Johnson*, 712 F.3d 549, 560 (Fed. Cir. 2013) (discussing the significance of "[e]xtensive, consistent usage in the specification" for claim construction).[5]

[5] To preempt confusion, the Court notes that its construction does *not* equate the injector to a single-use device that must be discarded after a single use. Rather, the Court finds that the claimed injector is capable of only delivering a single dose *at a time*, but may be capable of delivering multiple doses separately. (*See, e.g.*, '249 Patent at 2:45-46 (stating that there is a "processor coupled to the injector that records the date, the time, and the amount of each injection"); 9:3-7 ("In preferred embodiments,[] when activated, the microprocessor **32** displays the time and the amount of the last injection on the display **34** in an alternating sequence for 5 seconds . . . to remind the user of the last injection event."); 14:28-30 ("In preferred embodiments, the RAM **324** has a memory capacity for over . . . 100 injection administration events . . . .")).

Thus, to construe the disputed claim language such that more than one dose can be administered at a time, pursuant to a single injection, would "allow the claim language to become divorced from what the specification conveys is the invention." *See Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011). Although the portions of the prosecution history cited by Insulet seem to buttress the Court's analysis herein, the Court reaches its conclusion relying primarily on the '895 patent itself. *See Aventis Pharma*, 675 F.3d at 1331 ("The prosecution history can offer insight into the meaning of a particular claim term, but the claim language and the specification generally carry greater weight.") (internal quotations & textual modifications omitted).

But the Court must also reject a portion of Insulet's proposal. There is no claim language concerning physical insertion and withdrawal of a device. (*See, e.g.*, Claim 9 of the '249 Patent ("a medication injector for injecting a dosage of a medication"); Claim 48 ("[I]njecting a dosage of **[**a**]** the injectable substance into the individual's body using an injector in the medical device")). Indeed, the '249 patent explains that "embodiments of the present invention may be used with other types of injectors that are not pen shaped, such as jet injectors and the like." ('249 Patent at 5:32-34). And Insulet does not dispute that jet injectors use pressure to inject a substance through the skin *without* having to insert a needle or any other structure. (BD Open. Br. at 13 (citing expert declaration to this effect); Insulet Resp. Br. at 6-7 (not challenging this expert declaration)). To be sure, the Court is not persuaded that Insulet's insertion/withdrawal proposal is required by the patent's disclosure of a pen-type injection device *embodiment* that involves selection of an injection site, pushing the needle under the skin, delivery of a single dose of a medication, and withdrawal of the needle. *See Thorner*, 669 F.3d at 1365-66 ("It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner

in all embodiments, the patentee must clearly express an intent to redefine the term. . . . Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal. . . . It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation.") (internal quotations omitted).

Thus, the Court construes the disputed claim language as "a device that delivers a single dose at a time of a medication or injectable substance from outside a body to inside a body."

3. "processor" & "wherein the processor determines a value equal to the dosage of the medication to be injected by the medication injector, and wherein the processor determines blood characteristics from the non-perfusate blood sample analyzed by the blood characteristic monitor"

The term "processor" appears in independent Claims 9, 33 and 48 and various dependent claims of the '249 Patent.[6] The phrase "wherein the processor determines a value equal to the dosage of the medication to be injected by the medication injector, and wherein the processor determines blood characteristics from the non-perfusate blood sample analyzed by the blood characteristic monitor," or minor variations thereof, are found in independent Claims 9 and 33. These claims appear as follows in the '249 patent reexamination certificate (with bold typeface for the disputed claim language):

> 9. A medical device, comprising:
>
> a medical injector for injecting a dosage of a medication;
>
> a blood characteristic monitor for analyzing a *non-perfusate* blood sample;
>
> a **processor** coupled to the medication injector and the blood characteristic monitor, **wherein the processor determines a value equal to the dosage of the medication to be injected by the**

[6] The term "processor" is also found in independent Claims 1 and 11, as well as several dependent claims, of the '021 Patent. The parties agree that the construction of "processor" for the '249 patent applies to the '021 patent. (BD Open. Br. at 15 n.4; Insulet Open. Br. at 28-29).

medication injector, and wherein the processor determines blood characteristics from the *non-perfusate* blood sample analyzed by the blood characteristic monitor.

33. A portable medical device to maintain and monitor a condition of an individual's body, the device comprising:

an injector for injecting a dosage of an injectable substance into the individual's body;

a characteristic monitor for analyzing a *non-perfusate* fluid sample consisting of [saliva, urine or] blood removed from the individual's body;

a **processor** coupled to the injector and the characteristic monitor, **wherein the processor determines a value equal to the dosage of the injectable substance to be injected by the injector into the individual's body, and wherein the processor determines sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor.**

48. A method of maintaining and monitoring a condition of an individual's body with a portable medical device, the method comprising the steps of:

determining a value equal to a dosage of an injectable substance to be injected into the individual's body using a **processor** in the medical device;

injecting a dosage of [a] the injectable substance into the individual's body using an injector in the medical device;

removing a *non-perfusate* fluid sample consisting of [saliva, urine or] blood removed from the individuals body;

analyzing [a] *the non-perfusate* sample with a characteristic monitor in the medical device;

determining sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor with the processor in the medical device.

BD's Proposed Constructions:

(a) "Processor": "Circuitry that executes commands to perform desired operations"

(b) The "*wherein . . .*" clause*:* "The 'processor' (as defined above), regardless of whether it comprises one or more microprocessor chips, determines 'a value equal to the dosage of the medication to be injected by the medication injector' (as defined below) and determines blood sample characteristics, e.g. blood glucose levels"

Insulet's Proposed Constructions:

(a) "*Processor":* Plain meaning; Alternatively, "a microprocessor"

(b) The "*wherein . . .*" clause*:* "A single processor that (a) both determines blood sample characteristics (e.g., blood glucose levels) and (b) decides how much medication is to be injected into a patient"

Court's Constructions:

(a) "*Processor":* "Circuitry that executes commands to perform desired operations"

(b) The "*wherein . . .*" clause*:* "The processor, regardless of whether it comprises one or more microprocessor chips, determines 'a value equal to the dosage of the medication to be injected by the medication injector' and determines blood sample characteristics, e.g., blood glucose levels"

BD explains that the main disagreement concerning these two terms is over the scope of "processor." (BD Open. Br. at 17). BD argues that Insulet's proposal for "processor" requires the Court to determine what the "plain meaning" of processor is. (*Id.* at 15). BD asserts that Insulet's alternate proposal of "microprocessor" is an effort to advance a noninfringement position. (*Id.*). BD contends that the '249 patent specification "makes clear that, although a single microprocessor chip qualifies as a 'processor,' circuitry comprising multiple microprocessors is also a 'processor.'" (*Id.* at 15-16 (citing '249 Patent at 6:1-5)). BD references an embodiment in which the blood characteristic monitor analyzes blood characteristics and sends analysis results to the microprocessor, arguing that an ordinary artisan "would understand that, to analyze the blood characteristics and send the results, blood monitor 202 must include its own processing circuitry." (*Id.* at 16 (citing Anderson Decl. ¶ 13)). Finally,

BD relies on extrinsic evidence and argues that, at the time of the invention, "the term processor was used broadly to refer to circuitry relating to data processing, including various logic circuits that perform calculations or execute lines of computer code and associated memory circuits." (*Id.* at 16-17 (citing Anderson Decl. ¶ 12)).

As for the "wherein . . ." clause, BD argues that its proposal contemplates performance of the two claimed functions "by a processor comprising more than one chip." (*Id.* at 17-18). BD argues that another portion of Insulet's proposal (i.e., that the processor "decides how much medication is to be injected into a patient") is also incorrect because, in one embodiment, "the user sets the dosage by rotating a knob until the desired amount of medication is displayed." (*Id.* at 18 (citing '249 Patent at 7:57-67; 9:10-24; 10:36-40)). BD accordingly contends that a user decides how much medication is to be injected and the processor determines a value based on the user's decision. (*Id.*).

Insulet contends, however, that the "written description of the patent refers alternatively to the processor as a 'microprocessor.'" (Insulet Open. Br. at 17). Quoting a general purpose dictionary, Insulet explains that a microprocessor is "a computer processor contained on an integrated-circuit chip" or a "computer chip." (*Id.* (quoting Ex. 16 to Insulet Open. Br. at 736)). Insulet argues that the claim language requires that the "processor that is coupled to the medication injector and the blood characteristic monitor perform both of the functions required by the claim." (*Id.* at 18-19). In other words, Insulet argues that "the language of the claims clearly requires that a single processor be coupled to both the injection device and the blood characteristic monitor and that this microprocessor must perform both claimed functions." (*Id.* at 20 n.7).

Insulet also relies on the written description's repeated reference to "[t]he processor," (citing '249 Patent at 3:7-15), as well as Figure 15—a block diagram of the combined injector and blood characteristic monitor in which a single microprocessor is connected to, and serves, both the blood monitor and the injector. (Insulet Open. Br. at 19-20; Insulet Resp. Br. at 8). Insulet argues that just because the '249 patent "*discloses* a possible two processor alternative, does not establish that the patent claimed that alternative." (Insulet Resp. Br. at 9 (emphasis by Insulet)). Insulet also asserts that, during prosecution, the applicants distinguished prior art on the basis that a single processor performs both functions. (Insulet Open. Br. at 20). Notably, Insulet points to the applicants having distinguished the "Möstle reference" during reexamination, where they argued that the processor in the claimed invention "determines both (a) a value equal to the dosage of the medication, and (b) blood (or sample) characteristics from the blood . . . analyzed by the monitor." (*Id.* at 20-21 (quoting Ex. 18 to Insulet Open. Br. at 7)).

The parties do not seem to dispute that a single "processor" performs two functions: (1) "determines a value equal to the dosage of the medication to be injected by the medication injector"; and (2) "determines blood characteristics from the *non-perfusate* blood sample analyzed by the blood characteristic monitor." (Claim 9 of the '249 Patent). As BD correctly notes, however, the issue is "how you define a processor." (Tr. at 122:23-24). BD explains that, although the terms "processor" and "microprocessor" are used throughout the patent, the former "is a more general term[] that refers to any collection of processing functionality or circuitry" that "may or may not be a microprocessing." (*Id.* at 90:1-9 (explaining that a microprocessor is "a more specific type of processor" and a processor is a "more general term that describes something that does the processing functions")). Conversely, Insulet maintains that the term

microprocessor and the term processor are used interchangeably and that one microprocessor performs both claimed functions. (*Id.* at 100:15-22; 111:24-112:2).

The Court agrees with BD. "Claim terms are properly construed to include limitations not otherwise inherent in the term only when a patentee sets out a definition and acts as his own lexicographer, or when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Woods*, 692 F.3d at 1283 (internal quotations omitted). Here, the '249 patent's use of both "processor" and "microprocessor" is not sufficient to limit the scope of the "processor" claim language to a "microprocessor." *See Thorner*, 669 F.3d at 1365-66. Indeed, the patentee could have used "microprocessor" in the claims, but didn't.

Conversely, BD's proposal is consistent with the claim language because it permits a single "processor"—i.e., a "circuitry that executes commands to perform desired operations"—to perform the claimed two functions. BD's proposal is also consistent with a disclosed embodiment in which the device consists of a pen-type injector and a physically separate watch monitor that has a blood monitor. (*See* '249 Patent at 3:46-48; 13:52-54; 16:23-25). Indeed, Figure 4 (a flow block diagram for the pen-type injector) and Figure 23 (a flow block diagram for the blood monitor) indicate that *each* of these components could have a microprocessor. (*See also* '249 Patent at 6:1-5 ("The blood characteristic monitor uses the microprocessor in the pen-type injector (although a separate microprocessor could be used) to process the blood sample results and to store relevant information about the results.")). Thus, the specification does not reflect lexicography or intentional disavowal sufficient to narrow the claim scope of "processor" to a single microprocessor or limit a processor such that it cannot be composed of two microprocessors.

To be sure, the prosecution history does not support adopting Insulet's proposal. As discussed above, the applicants' representation that a single processor performs both claimed functions does not resolve the parties' dispute. Indeed, BD does not dispute that single processor performs both functions. (*See* BD Resp. Br. at 7-8). Rather, the issue is whether the processor is a microprocessor. And Insulet does not cite anything from the prosecution history suggesting clear disavowal of the "processor" language.

Finally, this analysis resolves the essential dispute over claim scope in the "wherein . . ." clause—i.e., "regardless of whether it comprises one or more microprocessor chips," (BD's proposal), versus "a single processor," (Insulet's proposal). Furthermore, the Court rejects Insulet's portion of the proposal that the "processor . . . decides how much medication is to be injected into a patient." As BD suggests, Insulet provides no basis for excluding an embodiment in which the user (and not the processor) sets the dosage. (*See* '249 Patent at 7:57-67; 9:10-24). The Court accordingly adopts BD's proposal for the disputed claim language (with minor variations, as provided above).

4. "coupled"

The parties dispute the meaning of this term that appears in independent Claims 9 and 33, as well as several dependent claims, from the '249 patent. Independent Claims 9 and 33 appear as follows in the '249 patent reexamination certificate (with bold typeface for the disputed claim language):

> 9. A medical device, comprising:
>
> a medical injector for injecting a dosage of a medication;
>
> a blood characteristic monitor for analyzing a *non-perfusate* blood sample;

> a processor **coupled** to the medication injector and the blood characteristic monitor, wherein the processor determines a value equal to the dosage of the medication to be injected by the medication injector, and wherein the processor determines blood characteristics from the *non-perfusate* blood sample analyzed by the blood characteristic monitor.
>
> 33. A portable medical device to maintain and monitor a condition of an individual's body, the device comprising:
>
> an injector for injecting a dosage of an injectable substance into the individual's body;
>
> a characteristic monitor for analyzing a *non-perfusate* fluid sample consisting of [saliva, urine or] blood removed from the individual's body;
>
> a processor **coupled** to the injector and the characteristic monitor, wherein the processor determines a value equal to the dosage of the injectable substance to be injected by the injector into the individual's body, and wherein the processor determines sample characteristics from the *non-perfusate* sample analyzed by the characteristic monitor.

BD's Proposed Construction: "Directly or indirectly connected, either wired, wirelessly, or mechanically"

Insulet's Proposed Construction: "Physically connected or attached, either directly or through intermediate structures"

Court's Construction: "Directly or indirectly connected, either wired, wirelessly, or mechanically"

In support of its proposal, BD cites a general purpose dictionary which defines "couple" as meaning "1. To link together; connect . . . 3. *Elect.* To link (two circuits or currents) as by magnetic induction." (BD Open. Br. at 18-19 (quoting Ex. N to BD Open. Br. at 318)). BD contends that, under this dictionary definition, "coupled means linked or connected and is not limited to physical contact." (*Id.* at 19). BD also references the specification's disclosure of wireless connections such as the watch monitor using infrared technology to upload program instructions and download information. (*Id.*). BD asserts that "nothing in the specification

excludes wireless connections." (*Id.*). BD thus argues that, "[a]lthough 'coupled' includes a physical connection, the patent and its prosecution do not exclude a wireless connection from the meaning of 'coupled.'" (BD Resp. Br. at 10). Finally, BD relies on expert testimony and argues that an ordinary artisan would understand "coupled" as being "used to refer to the electromagnetic connection between antennas or apparatuses that communicate using antennas." (BD Open Br. at 19 (citing Anderson Decl. ¶ 14); *see also* BD Resp. Br. at 9 ("BD's expert also testified that a skilled artisan would understand 'coupled' to include wireless connections. Since that testimony is unrebutted, this Court should credit it entirely.") (internal citations omitted)). BD also cites Insulet's own documents in which Insulet's engineers allegedly "repeatedly refer to the wireless connection between the components (or their respective antennas) as coupling." (BD Open Br. at 19).

Insulet, however, argues that requiring a physical connection of some type is consistent with the way "coupled" is used throughout the '249 patent. (Insulet Open. Br. at 22). Insulet explains that there are "nearly fifty separate uses of the word 'coupled' in the written description of the '249 patent" and that, "[i]n each instance, the term refers to components that are physically connected, either directly or through intermediate structures." (*Id.*). Specifically, Insulet argues that the block diagram of the combined medication injector and blood characteristic monitor in Figure 15 "shows a single microprocessor physically connected to, and contained within the same housing as, both the medication injector and the characteristic monitor." (*Id.*). Insulet contends that such physical connection "is what allows the combined pen-type injector and blood characteristic monitor to be an 'all-in-one' device." (*Id.*). Insulet further argues that when the '249 patent describes situations where a device merely communicates or coordinates with another device—i.e., communication between a pen-type injector and a computer,

communication between a watch monitor and a computer, and communication from a pen-type injector to a watch monitor—it does *not* use the "coupled" language. (*Id.* at 23). Thus, Insulet asserts that "there is no suggestion whatever [sic] that a processor in one structure might be 'coupled' wirelessly with either an injector or a blood characteristic monitor in another structure that is at a remote location." (Insulet Resp. Br. at 11). Accordingly, Insulet insists that BD's construction is "inconsistent with the actual usage of the word 'coupled' in the '249 patent, with the fact that the patent does not use the word 'coupled' when it describes devices that merely communicate or cooperate with each other, and with the further fact that wireless communication is never mentioned in the '249 patent." (Insulet Open Br. at 23).

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *See Phillips*, 415 F.3d at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.* Furthermore, as previously noted, "[c]laim terms are properly construed to include limitations not otherwise inherent in the term only when a patentee sets out a definition and acts as his own lexicographer, or when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Woods*, 692 F.3d at 1283 (internal quotations omitted).

Given these principles, the Court construes "coupled" as "directly or indirectly connected, either wired, wirelessly, or mechanically." The Court is not convinced that "coupled" should be narrowed to mean only physically connected or attached because there is no lexicography or clear disavowal to this effect. Even accepting Insulet's argument that "coupled" is only used when referring to physical connection, this is insufficient. *See Thorner*, 669 F.3d at

1365-66 ("It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to redefine the term. . . . [For clear disavowal,] [i]t is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation."). As BD correctly observes, "coupled" may cover the physical connection allegedly disclosed in Figure 15. But only the patentee can redefine "coupled" to mean *only* a physical connection. Here, the patentee has not done so and the Court refuses to now do so. Indeed, the dictionary definition of "coupled" is consistent with the intrinsic record and supports BD's proposal. *Phillips*, 415 F.3d at 1322-23 ("[J]udges are free to consult dictionaries and technical treatises 'at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.'") (quoting *Vitronics*, 90 F.3d at 1584 n.6).

5. "program instructions"

The parties dispute the meaning of this term from dependent Claims 22, 23, 41, 46, 47, and 49 of the '249 patent.[7] For example, dependent Claims 22 and 23 are as follows (with bold typeface for the disputed claim language):

> 22. A device according to claim **9**, further including a data port coupled to the processor that is used to transfer **program instructions** from an external [programing] *programming* device to the processor.
>
> 23. A device according to claim **22**, wherein the data port uses infrared energy to transfer the **program instructions**.

And Claim 1 of the '021 patent is as follows (with bold typeface for the disputed claim language):

[7] This term also appears in independent Claims 1 and 11, as well as in certain dependent claims, of the '021 patent. The parties agree that "program instructions" has the same meaning in the '249 and '021 patents. (*See* BD Open. Br. at 24; Insulet Open. Br. at 36-37 n.13; Insulet Resp. Br. at 11-12).

> 1. A medical monitor, comprising:
>
> a portable housing;
>
> a characteristic monitor contained in the portable housing for analyzing a characteristic sample;
>
> a processor coupled to the characteristic monitor, wherein the processor includes determining means for determining characteristics based on the analyzed characteristic sample from the characteristic monitor; and
>
> a data port coupled to the processor, wherein the data port includes transferring means for transferring data and **program instructions** from a medication delivery device to the processor,
>
> wherein the processor includes means for using the characteristics and the data from the medication delivery device to compare the characteristics and data to determine if the medical regimen is correct and whether modifications to the medical regimen are required.

BD's Proposed Construction: "Signals commanding a processor to perform an operation"

Insulet's Proposed Construction: "Instructions regarding the quantity of medication to be injected and/or the timing of injections (i.e., instructions that establish or modify the treatment regimen)" *modified at oral argument to* "Directions provided to a device by a user or a doctor"

Court's Construction: "Signals commanding a processor to perform an operation"

BD argues that the '021 patent provides disclosures in which the "medicine delivery component sends signals to a processor to perform an operation" and that "[t]hese signals direct the processor to 'store relevant information concerning the injection,' 'display[] the time and the amount of the last injection,' and to 'activate.'" (BD Open. Br at 24 (quoting '021 Patent at 8:58-59, 10:4-5, 8:22-25) (internal citations omitted)). BD contends that "Insulet creates a narrow construction by improperly reading in limitations that are, at best, referenced in the patent as permissive examples of the term 'program instructions.'" (*Id.* at 25).

At the *Markman* hearing, Insulet revised its proposal to "directions provided to a device by a user or a doctor." (Tr. at 146:9-11; *see also* 143:6-21). In support of its revised proposal, Insulet cites the following three "examples" from the '249 patent, (*id.* at 145:4-23):

> 1. "The data I/O port **46** is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor," ('249 Patent 8:26-29);
>
> 2. "If required, the doctor can update the program instructions in the pen-type injector **10** via the data I/O port **46** to provide reminder alarms at various times," (*id.* at 9:43-45);
>
> 3. "The data I/O port **320** is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor," (*id.* at 14:45-48).

Insulet argues that BD's own expert testimony supports Insulet's proposal. (Tr. at 145:24-146:6). BD counters that Insulet's proposal fails to describe what the "program instructions" are and, instead, describes where they came from. (*Id.* at 146:14-18). Insulet insists, however, that "program instructions are instructions from a doctor, patient, or another part of the claimed device, that direct a processor to execute a particular operation." (Insulet Resp. Br. at 11-12).

The Court is not convinced that "program instructions" should be limited to only those directions provided by a user or doctor because neither the '249 patent nor the '021 patent provides lexicography or clear disavowal to that extent. *See Woods*, 692 F.3d at 1283. Specifically, the Court finds that the three examples Insulet cites are insufficient to so limit "program instructions." *See Thorner*, 669 F.3d at 1365-66. Given the disclosures in the '249 and '021 patents, the Court adopts BD's proposal, "signals commanding a processor to perform an operation." Indeed, aside from the "by a user or a doctor" portion of its proffered construction at the *Markman* hearing, Insulet seems to agree with BD's proposal. (*See* Insulet

Resp. Br. at 11-12 ("There is little difference between the parties with respect to [program instructions]. Insulet agrees that program instructions are instructions from a doctor, patient, or another part of the claimed device, *that direct a processor to execute a particular operation*.") (emphasis added)).[8]

B. Disputed Claim Terms in the '021 Patent

The parties dispute the meaning of several terms from the '021 patent. These terms appear in certain claims of the '021 patent as follows (with bold typeface for the disputed claim language):

> 1. A medical monitor, comprising:
>
> a portable housing;
>
> a characteristic monitor contained in the portable housing for analyzing a characteristic sample;
>
> a processor coupled to the characteristic monitor, wherein **the processor includes determining means for determining characteristics based on the analyzed characteristic sample from the characteristic monitor**;[9] and
>
> **a data port** coupled to the processor, **wherein the data port includes transferring means for transferring data and program instructions from a medication delivery device to the processor**,[10]
>
> wherein **the processor includes means for using the characteristics and the data from the medication delivery device to compare the characteristics and data to determine if**

[8] As for the remaining disputed terms from the '249 patent (raised in BD's briefing), "Insulet accepts BD's proposed construction of the phrases 'a value equal to the dosage,' 'means to determine the date' and 'means to provide an alarm indication at a predetermined time.'" (Insulet Open. Br. 24-25 n.11). Insulet also accepts BD's proposal for this third term ("means to provide an alarm indication at a predetermined time") as it concerns the '021 patent. (*Id.* at 36-37 n.13).

[9] Insulet proposes construing "the processor includes" portion of this disputed claim term, but BD does not. (BD Open Br. at 25 n.11; Insulet Open. Br. at 28). This disparity also exists for this term in Claim 11 below.

[10] Insulet proposes construing "a data port . . . wherein the data port includes" portion of this disputed claim term, but BD does not. (BD Open Br. at 29 n.13; Insulet Open. Br. at 33).

the medical regimen is correct and whether modifications to the medical regimen are required.[11]

2. **A medical monitor according to claim 1, wherein transferring means of the data port coupled to the processor is used to transfer data from the processor to the medication delivery device**.[12]

11. A medical monitor, comprising:

a portable housing;

a characteristic monitor contained in the portable housing for analyzing a characteristic sample;

a processor coupled to the characteristic monitor, wherein **the processor includes determining means for determining characteristics based on the analyzed characteristic sample from the characteristic monitor**; and

a data port coupled to the processor, **wherein the data port includes transferring means for transferring the characteristics from the processor to a medication delivery device and to receive data from the medication delivery device**,[13]

wherein **the processor include means for using the characteristics and the data from the medication delivery device to compare the characteristics and data to determine if the medical regimen is correct and whether modifications to the medical regimen are required**.

12. A medical monitor according to claim 11, wherein **the transferring means of the data port coupled to the processor is used to transfer data from the medication delivery device to the processor.**

[11] Insulet proposes construing "the processor includes" portion of this disputed claim term, but BD does not. (BD Open Br. at 33 n.15; Insulet Open. Br. at 29). This disparity also exists for this term in Claim 11 below.

[12] Insulet proposes construing "a medical monitor according to claim 1, wherein" portion of this disputed claim term, but BD does not. (BD Open Br. at 29; Insulet Open. Br. at 34).

[13] Insulet proposes construing "a data port . . . wherein the data port includes" portion of this disputed claim term, but BD does not. (BD Open Br. at 30 n.14; Insulet Open. Br. at 35).

The parties agree that these disputed terms invoke a means-plus-function analysis under 35 U.S.C. § 112. (BD Open Br. at 26, 28, 33; Insulet Open. Br. at 27). But Insulet argues that these means-plus-function claim limitations are indefinite and, therefore, that the claims are invalid. (Insulet Open. Br. at 28, 29, 33, 34, 36).

By statute, a patentee may express a claimed element as a "means or step for performing a specified function without the recital of structure, material, or acts in support thereof." 35 U.S.C. § 112 ¶ 6. The statute thereby establishes a *quid pro quo* by allowing inventors to "use a generic means expression for a claim limitation" if "the specification indicates what structure(s) constitute(s) the means." *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1381 (Fed. Cir. 1999). And, "[i]f the word 'means' appears in a claim element in association with a function, th[e] court presumes that § 112, ¶ 6 applies." *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1257 (Fed. Cir. 1999).

Claim construction of terms which invoke a means-plus-function analysis involves two steps. "First, the court must determine the claimed function." *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1332 (Fed. Cir. 2006). Once the function is identified, the court "construe[s] the meaning of the words used to describe the claimed function, using ordinary principles of claim construction." *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1319 (Fed. Cir. 2003).

Next, "the court must identify the corresponding structure in the written description of the patent that performs that function." *Applied Med. Res. Corp.*, 448 F.3d at 1332. "The specification must be read as a whole to determine the structure capable of performing the claimed function." *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379 (Fed. Cir. 2001). Importantly, a "structure disclosed in the specification is corresponding structure only if the

specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1367 (Fed. Cir. 2012) (quoting *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 (Fed. Cir. 2003)). If, however, an ordinary artisan "would be unable to recognize the structure in the specification and associate it with the corresponding function in the claim," then the means-plus-function clause is indefinite under 35 U.S.C. § 112 ¶ 2 and ¶ 6. *AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1241 (Fed. Cir. 2007).

As Insulet conceded at the *Markman* hearing, however, the Court finds that Insulet's indefiniteness arguments are more appropriately addressed at summary judgment or trial. (Tr. at 128:4-5 ("[T]his was the wrong occasion to argue indefiniteness, which is an invalidity argument, and I agreed to that.")); *see Presidio Components, Inc. v. Am. Technical Ceramics Corp.*, No. 07-893, 2008 WL 2397488, at *3 (S.D. Cal. June 11, 2008) ("As an initial matter, the Court declines to address ATC's indefiniteness argument at this point with respect to this and other disputed terms and concludes such analysis would be more appropriate at the summary judgment stage."); *Intergraph Hardware Techs. Co. v. Toshiba Corp.*, 508 F. Supp. 2d 752, 773 n.3 (N.D. Cal. 2007) ("The parties appear to agree on the corresponding structure, though Toshiba argues that the structure is too indefinite. This indefiniteness argument is inappropriate at the claim construction stage."); *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, No. 02-148, 2003 WL 124149, at *1 n.1 (D. Del. Jan. 13, 2003) ("Consistent with the court's oral ruling during the *Markman* hearing . . . the court will not address the defendants' indefiniteness argument at this stage of the proceedings."); *see also Alcon Research, Ltd. v. Barr Labs. Inc.*, No. 09-0318, 2011 WL 3901878, at *16 (D. Del. Sept. 6, 2011) ("We find that the indefiniteness issue is best decided at trial and defer consideration on it until that time.").

To be sure, it is not apparent from the parties' briefing and oral argument at the *Markman* hearing whether (and to what extent) the parties dispute the scope of the language that reflects the function in the above-mentioned means-plus-function limitations. (*See* Insulet Open. Br. at 28, 29, 33, 34, 35, 36; *see also* Tr. at 127:25-28:1 ("[T]here is not much disagreement between us as to what the functions are . . . ."); Tr. at 156:15-157:2 ("Our proposed functional definition is very close to [BD's] . . . . If Your Honor thinks lay people wouldn't have an easier time with it, I could not criticize lifting the words directly out of the claim.")). Accordingly, the Court defers construing the meaning of the words used to describe the claimed functions (to the extent necessary) until Insulet raises its indefiniteness challenges.

In sum, the Court declines to address Insulet's indefiniteness arguments at this stage and defers such analysis, as well as any attendant claim construction tasks, until a later time.

C. Disputed Claim Terms in the '895 Patent

1. "reservoir"

The parties dispute the meaning of this term from several claims of the '895 patent, including asserted Claims 14 and 16. These asserted claims are as follows (with bold typeface for the disputed claim language):

> 14. A device for delivering a liquid theraputic [sic] preparation into the body of a patient by injection into or through the skin, comprising:
>
> a low-profile housing having a bottom surface adapted to be brought into contact with the skin of a patient, said bottom surface having a needle aperture therein, said housing being sufficiently low in height to allow said device to be worn inconspicuously under the clothing of the patent [sic];
>
> a **reservoir** disposed within said housing for containing a liquid theraputic [sic] preparation;

> an injection needle disposed generally horizontally in said housing and adapted to communicate with said **reservoir**, said injection needle having a bent injection end adapted to project through said needle aperture; and
>
> a movable needle carrier disposed in said housing for carrying said injection needle and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier;
>
> wherein said needle carrier and said injection needle are disposed in a side-by-side relationship with said **reservoir** in said housing in order to minimize the height of said housing above said bottom surface.
>
> 16. A device as claimed in claim **14**, wherein said **reservoir** is held at a fixed position within said housing.

BD's Proposed Construction: "A container in which liquid is held"

Insulet's Proposed Construction: "A container that empties itself without need for a pump or other type of discharge device"

Court's Construction: "A container that empties itself without need for a pump or other type of discharge device"

BD argues that its proposal is consistent with the claim language since Claim 14 does not limit "reservoir" to a self-emptying reservoir. (BD Open. Br. at 40-41). Relying on claim differentiation, BD contends that dependent Claim 17[14] and independent Claim 18[15]—which purportedly have certain limitations relating to automatic discharge from the reservoir—suggest that the "reservoir" from Claims 14 and 16 is not limited as Insulet proposes. (*Id.* at 40). BD

[14] Claim 17 is as follows: "A device as claimed in claim **14**, wherein said reservoir is resiliently expandable in order to exert pressure on a liquid theraputic [sic] preparation contained therein, whereby said liquid theraputic [sic] preparation is automatically discharged from said reservoir."

[15] Claim 18 is as follows: "A device for delivering a liquid theraputic [sic] preparation into the body of a patient by injection into or through the skin of the patient comprising: a housing adapted to be held in contact with the skin of a patient; a reservoir disposed within said housing for containing a liquid theraputic [sic] preparation, said reservoir including a Belleville spring which exerts pressure on said liquid theraputic [sic] preparation to discharge said liquid theraputic [sic] preparation from said reservoir at a relatively constant rate; and an injection needle adapted to communicate with said reservoir and to project from said housing in order to inject said liquid theraputic [sic] preparation into or through the skin of the patient."

argues that, "even though the specification discusses self-emptying reservoirs," ordinary artisans do not understand the disputed claim language to mean *only* a self-emptying container. (*Id.* at 41). Indeed, BD argues that the written description refers to reservoirs in other patents that require a separate mechanism to discharge liquid and are not capable of emptying themselves without a pump or other discharge device. (*Id.* (citing '895 Patent at 1:16-28)). BD also contends that Figure 12 of the '895 patent is an example of a reservoir that is unable to empty itself because liquid is discharged only by external forces—i.e., by Belleville washers that are outside of the membranes that make up the reservoir. (BD Resp. Br. at 19).

Finally, BD points to a related patent, U.S. Patent No. 6,074,369, where "the patentee required the reservoir to comprise Belleville springs in all claims," whereas here, Claim 14 "includes no language directed to the discharge features of the 'reservoir.'" (BD Open. Br. at 40-41). Accordingly, BD contends that Insulet's proposal improperly imports limitations from the specification into the claim language. (*Id.* at 41). BD stresses that it is improper to limit claim language just because the only disclosed embodiment has a particular feature. (*Id.* at 42).

Insulet, however, cites the following language from the written description: "*the invention* . . . incorporates a self-emptying reservoir." (Insulet Open. Br. at 41 (quoting '895 Patent at 1:8-15) (emphasis by Insulet)). Insulet asserts that the self-emptying feature is "central to the purpose of the invention." (*Id.*). Indeed, Insulet explains that this feature is an improvement over the prior art "because it eliminates the need for a pump to cause liquid to flow out of the reservoir and into the patient, thus reducing the cost, size, and complexity of the device." (*Id.* (citing '895 Patent at 1:60-2:20)). Insulet adds that the "Summary of the Invention" characterizes an aspect of the invention as having a reservoir that includes a spring, which exerts pressure on the liquid in the reservoir when the reservoir is penetrated by the

injection needle. (*Id.* (citing '895 Patent at 3:9-18 & 7:55-58)). And Insulet explains that both of the disclosed embodiments incorporate a self-emptying reservoir. (*Id.*). Insulet thus asserts that its proposal "tether[s] the claims to what the specification[] indicate[s] the inventor actually invented." (*Id.* at 42-43 (quoting *Retractable Techs.*, 653 F.3d at 1305).

The Court disagrees with BD that the "claim language is about as far as [the Court] needs to go to" ascertain the scope of the term "reservoir," (Tr. at 186:1-5). *See Phillips*, 415 F.3d at 1314-15. As such, "the specification is always highly relevant to the claim construction analysis" and it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1315, 1317 (internal quotations omitted); *see also Retractable Technologies*, 653 F.3d at 1305 ("It is axiomatic that the claim construction process entails more than viewing the claim language in isolation. Claim language must always be read in view of the written description and any presumption created by the doctrine of claim differentiation will be overcome by a contrary construction dictated by the written description or prosecution history.") (internal quotations & citations omitted).

The Court adopts Insulet's proposal. The title of the '895 patent is "Low-Profile Automatic Injection Device with Self-Emptying Reservoir." The specification accordingly provides as follows:

> More particularly, the invention relates to a low-profile automatic injection device that can be worn inconspicuously under the clothing of a patient to allow a liquid theraputic [sic] preparation (such as insulin) to be administered over an extended period of time, *and that incorporates a self-emptying reservoir to eliminate the need for a pump or other type of discharge device*.

('895 Patent at 1:8-15 (emphasis added)). The specification explains that, "in accordance with a still further aspect of the present invention," a "reservoir is disposed within the housing for

containing a liquid theraputic [sic] preparation to be administered" and that the "reservoir includes a Belleville spring which exerts pressure on the liquid theraputic [sic] preparation to discharge the liquid theraputic [sic] preparation from the reservoir at a relatively constant rate." (*Id.* at 3:13-18). Indeed, the specification criticizes the prior art as follows:

> Unfortunately, most of the automatic infusion devices disclosed in the prior art are fairly complex in design and, as a result, cannot be made as small and inexpensive as might be desired. Generally, the complexity of these devices results from three factors. *One factor is the need for a pump or other type of discharge mechanism to force the liquid theraputic [sic] preparation to flow out of the reservoir and into the injection or infusion needle.*

(*Id.* at 1:60-67 (emphasis added)).

To be sure, the Court is not persuaded otherwise by BD's argument that the specification references other patents that do not disclose self-emptying reservoirs. (*See* BD Open. Br. at 41 (citing '895 Patent at 1:16-28)). As Insulet correctly notes, the '895 patent seems to distinguish the devices that have those reservoirs from the instant invention. (*See* '895 Patent at 1:64-2:9). Furthermore, in view of the statements in the '895 patent specification discussed above, the Court is not convinced that "reservoir" should mean both self-emptying and non-self-emptying given the scope of the claims in the related U.S. Patent No. 6,074,369. *See Aventis Pharma*, 675 F.3d at 1331 ("The prosecution history can offer insight into the meaning of a particular claim term, but the claim language and the specification generally carry greater weight.") (internal quotations & textual modifications omitted). Indeed, the claims of that related patent seem to cover a particularly defined mechanism for self-emptying (i.e., that using Belleville springs) and thus do not indicate that "reservoir" in the '895 patent means both self-emptying and not self-emptying. (*See* Ex. AA to Melwani Decl. at Claims 1, 8, 16).

Furthermore, the Court is not persuaded that Figure 12 of the '895 patent warrants adopting BD's proposal. In the Figure 12 embodiment, "the liquid reservoir **118** comprises two flexible membranes **120** and **122**" and a "Belleville washer **124** with a hollow center **126** is bonded to the outside of the top membrane **120**, and a similar Belleville washer **128** . . . with a hollow center **130** is bonded to the outside of the bottom membrane **122**." ('895 Patent at 9:39-45). Notably, the specification explains that, "[e]xcept for their hollow centers **126** and **130**, the Belleville washers **124** and **128** are *similar in construction and function* to the Belleville spring diaphragms **102** and **104** shown in FIGS. **9-11**." (*Id.* at 9:45-48 (emphasis added)). In fact, "the sole function of the Belleville washers **124** and **128** is to pressurize the liquid theraputic [sic] preparation contained within the liquid reservoir **118** . . . ." (*Id.* at 9:49-52). Thus, it is not apparent that the reservoir disclosed in Figure 12 is unable to empty itself as BD posits. It seems equally, if not more likely, that the Belleville washers in the Figure 12 embodiment function like the Belleville springs of Figure 9, in which the pressure exerted by the Belleville springs "causes the liquid theraputic [sic] preparation **100** to be discharged through the injection needle **54** without the need for a pump or other type of discharge device." (*See id.* at 9:7-11).

Finally, the Court is also not persuaded otherwise by BD's claim differentiation argument relating to dependent Claim 17 and independent Claim 18. As Insulet again correctly explains, claim differentiation would *not* be violated by construing "reservoir" to mean "a container that empties itself without need for a pump or other type of discharge device" because dependent Claim 17 and independent Claim 18 cover particularly defined mechanisms whereby self-

emptying is achieved. In other words, dependent Claim 17 and independent Claim 18 do not simply claim self-emptying reservoirs.[16]

In sum, the Court finds that adopting BD's proposal would effectively divorce the claim language from the rest of the patent. Accordingly, in view of the specification, the Court finds that the self-emptying feature is an inherent limitation in the term "reservoir." *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1342-44 (Fed. Cir. 2001) (finding disclaimer of subject matter and construing claim language accordingly).

2. "injection needle"

The parties dispute the meaning of this term found in asserted Claim 14 of the '895 patent, which appears as follows (with bold typeface for the disputed claim language):

> 14. A device for delivering a liquid theraputic [sic] preparation into the body of a patient by injection into or through the skin, comprising:
>
> a low-profile housing having a bottom surface adapted to be brought into contact with the skin of a patient, said bottom surface having a needle aperture therein, said housing being sufficiently low in height to allow said device to be worn inconspicuously under the clothing of the patent [sic];
>
> a reservoir disposed within said housing for containing a liquid theraputic [sic] preparation;
>
> an **injection needle** disposed generally horizontally in said housing and adapted to communicate with said reservoir, said **injection needle** having a bent injection end adapted to project through said needle aperture; and
>
> a movable needle carrier disposed in said housing for carrying said **injection needle** and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier;

[16] BD's argument at the *Markman* hearing is telling. It argued that "there is not a lot of room between [Insulet's] proposed construction and [C]laim 17." (Tr. at 196:7-8). BD did not, however, assert that there is *no* room such that Claim 17 would be superfluous and claim differentiation would be violated.

> wherein said needle carrier and said **injection needle** are disposed in a side-by-side relationship with said reservoir in said housing in order to minimize the height of said housing above said bottom surface.

BD's Proposed Construction: "A hollow needle that pierces skin and is a conduit for fluid delivery"

Insulet's Proposed Construction: "A needle that, while inserted into the body of a patient, delivers a therapeutic preparation"

Court's Construction: "A needle that, while inserted into the body of a patient, delivers a therapeutic preparation"

BD explains that the parties' dispute "centers on whether fluid delivery must occur while the needle is in a patient's body, as proposed by Insulet." (BD Open. Br. at 42). BD asserts, however, that the intrinsic evidence simply does not support Insulet's proposal. (*Id.*). BD contends that the '895 patent "provides instances when there is no fluid delivery while the needle is in the body." (*Id.*). BD cites an example in which the needle is in the patient, but a valve can be closed such that liquid does not flow through the needle. (*Id.* (citing Figure 8 and 8:9-15 of the '895 Patent)). Similarly, BD explains that, when the reservoir has emptied, but the device remains secured to the patient, liquid does not flow through the needle. (*Id.*). And BD argues that Insulet's own patent, U.S. Patent No. 6,485,461, uses "injection needle" in a way that contradicts its position here. (BD Resp. Br. at 21; *see also* D.E. No. 79, BD's Supplemental *Markman* Brief ("BD Supp. Br.") at 6 ("Insulet's patent supports the idea that an 'introducer needle' is, or is a type of, 'injection needle.'")).

Insulet asserts, however, that the '895 patent describes an injection needle "that is inserted in a patient's body and delivers a therapeutic preparation to the patient while in the patient's body." (Insulet Open. Br. at 43 (citing '895 Patent at 7:30-43 & 9:16-20)). Insulet explains that the specification teaches that "the needle carrier of the invention forces the forward

portion of the injection needle downward so that it penetrates the patient's skin." (Insulet Resp. Br. at 20 (citing '895 Patent at 6:21-24 & 6:63-7:4)). At that time, Insulet explains that "medication 'begin[s] to flow through the injection needle into the body of the patient.'" (*Id.* (quoting '895 Patent at 2:45-53) (textual modification by Insulet)). Citing Figure 6, Insulet asserts that the "needle remains in the patient at all times when medication is being delivered" and that the "only other embodiment disclosed in the '895 patent similarly includes an injection needle that delivers medication while in the patient's body." (*Id.* (citing '895 Patent at 10:4-5; 10:18-11:10)). Insulet also contends that the words of Claim 14 are consistent with its proposal. (*Id.*).

Insulet additionally argues that Mr. Robert Connelly, an inventor of the '895 patent, testified that an "introducer needle" is *not* used to inject a therapeutic substance into a patient. (D.E. No. 74, Insulet's Supplemental *Markman* Brief ("Insulet Supp. Br.") at 6-7). Insulet points to this testimony because it seems to argue that BD's proposal is designed to capture devices that deliver medication through implantation of a cannula—devices which, according to Insulet, are called "insertion needles" or "introducer needles." (Insulet Open. Br. at 43-44). Insulet therefore seems to argue that Mr. Connelly's testimony undermines BD's proposal because BD's proposal would capture devices that are not contemplated by the '895 patent. (*See* Insulet Supp. Br. at 6-7; *see also* Insulet Resp. Br. at 20 ("The patent does not describe a needle that merely carries a soft cannula into a patient's body and is withdrawn from the patient before any medication is delivered.")).

The Court adopts Insulet's proposal. BD characterizes the issue as "whether fluid delivery must occur while the needle is in a patient's body." (BD Open. Br. at 42). But BD misstates the issue. The issue is whether the needle must be in a patient's body for fluid delivery

to occur, *not* whether fluid delivery must occur when the needle is in a patient's body. Indeed, it seems plausible that the valve can be closed or that the reservoir can be empty such that the needle remains in a patient's body without fluid delivery. But, for fluid delivery to occur, the '895 patent consistently and repeatedly explains that the injection needle must be inserted into the patient. Specifically, it explains that the "injection needle" has a portion which is "for penetrating the skin of the patient, and a second portion . . . for communicating with the reservoir." ('895 Patent at 2:37-41). And "movement of the needle carrier between the first and second positions causes the injection needle to penetrate the skin of the patient, and also causes the liquid theraputic [sic] preparation to begin to flow through the injection needle into the body of the patient." (*Id.* at 2:49-53).

Furthermore, according to the embodiment described in Figure 6, the injection needle "penetrates the skin of the patient" and, ultimately, "a flow path is established between the reservoir **50** and the body of the patient through the lumen of the injection needle **54**." ('895 Patent at 7:33-43). Likewise, in the embodiment described in Figure 13, the specification explains that, after the "distal end of the injection needle **142** . . . project[s] from a needle aperture **166**," the "liquid theraputic [sic] preparation is then automatically discharged from the reservoir **118** through the injection needle **142** in the same manner as in the previous embodiment." (*Id. at* 10:42-52). "After the liquid theraputic [sic] preparation has been completely discharged from the reservoir **118**, the automatic injection device **116** can be removed from the body of the patient . . . ." (*Id. at* 10:64-66).

Therefore, construing "injection needle" to mean a needle that must be inserted into the body of a patient for a therapeutic preparation to be delivered "most naturally aligns with the patent's description of the invention." *See Saffran*, 712 F.3d at 560 (quoting *Ormco Corp. v.*

Align Tech., Inc., 498 F.3d 1307, 1313 (Fed. Cir. 2007)); *see also Phillips*, 415 F.3d at 1323 (recognizing that, in certain situations, "it will become clear . . . [that] the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive"). BD's proposal falls short because its proposal—"a hollow needle that pierces skin and is a conduit for fluid delivery"—does not require the needle to be in a patient to achieve fluid delivery, which seems to be described as a fundamental feature of the invention. *See Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003) ("[W]here the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims."). To be sure, given the specification's teachings discussed above, the Court is not persuaded otherwise by BD's reliance on Insulet's characterization of "injection needle" in extrinsic evidence (i.e., U.S. Patent No. 6,485,461). *See Phillips*, 415 F.3d at 1319 ("[E]xtrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.").

3. "an injection needle . . . adapted to communicate with said reservoir"

The parties dispute the meaning of this term again found in asserted Claim 14 of the '895 patent, which appears as follows (with bold typeface for the disputed claim language):

> 14. A device for delivering a liquid theraputic [sic] preparation into the body of a patient by injection into or through the skin, comprising:
>
> a low-profile housing having a bottom surface adapted to be brought into contact with the skin of a patient, said bottom surface having a needle aperture therein, said housing being sufficiently low in height to allow said device to be worn inconspicuously under the clothing of the patent [sic];
>
> a reservoir disposed within said housing for containing a liquid theraputic [sic] preparation;

> **an injection needle** disposed generally horizontally in said housing and **adapted to communicate with said reservoir**, said injection needle having a bent injection end adapted to project through said needle aperture; and
>
> a movable needle carrier disposed in said housing for carrying said injection needle and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier;
>
> wherein said needle carrier and said injection needle are disposed in a side-by-side relationship with said reservoir in said housing in order to minimize the height of said housing above said bottom surface.

BD's Proposed Construction: "An injection needle that receives fluid from the reservoir"

Insulet's Proposed Construction: "An injection needle that may be moved so as to bring it into fluid communication with the reservoir" *modified in responsive briefing to* "An injection needle that is constructed and arranged in a way that allows it to be moved from a position where the needle is not in fluid communication with the reservoir of the device to a position where it is in communication with that reservoir"

Court's Construction: "An injection needle that receives fluid from the reservoir"

In response to Insulet's revised proposal, BD argues that Insulet is relying on an "aspect of the invention" that is embodied in *unasserted* claim 1, "almost word-for-word." (BD Supp. Br. at 8 (citing '895 Patent at 2:23-53)). And BD asserts that the "aspect of the invention" at issue in this case—i.e., relating to *asserted* Claim 14—is summarized at a different portion of the specification. (*Id.* (citing '895 Patent at 2:54-3:8)).

Furthermore, BD argues that the "adapted to" language "has a well understood meaning in patent law." (*Id.*). BD contends that, under case law, "adapted to" is construed "much more broadly than either of Insulet's proposed constructions, which import additional features into the claim that go far beyond the recognized meaning of the term 'adapted to.'" (*Id.* at 8-9). Indeed, BD contends that, where the patentee wanted to reference a particular movement in the claims, it

did so. (*Id*. at 9-10 (citing Claim 14 and emphasizing the "upon movement" language); *see also* Tr. at 207:3-12 ("There are other parts of the claim that you talk about movement . . . . [W]hen the claim wants to require a particular movement in order to accomplish something, it actually said it . . . ."). Accordingly, BD asserts that "there is no reason to presume that the patentee intended that movement be implicit in this claim limitation" and that "[s]tructure permitting fluid communication is all that is necessary to meet 'adapted to communicate' language." (BD Supp. Br. at 9-10). Finally, BD stresses that the "preferred embodiment discloses many characteristics that may aid in adapting the needle to communicate with the reservoir" but that "[t]hese characteristics . . . are not recited in [C]laim 14 and do not limit it." (*Id.* at 10).

Insulet argues that its revised proposal "encapsulates what the Summary Of The Invention portion of the '895 patent calls an 'aspect of the invention.'" (Insulet Resp. Br. at 21 (citing '895 Patent at 2:23-49)). Insulet explains that the central feature of the claimed device is a combination of "(1) an injection needle that, in a first position, is not in fluid communication with a reservoir (and is not inserted in a patient) and, in a second position, is in fluid communication with a reservoir (and is inserted in a patient), plus (2) a reservoir that empties itself once a fluid path is opened." (*Id.*). Insulet avers that BD's proposal would capture far more than what the patent describes and gives no meaning to the "adapted to" language of the term. (*Id.*). And Insulet asserts that "BD does not even attempt to explain why it believes that its construction either fits with the words of the claim or fairly captures the supposed invention of the patent." (*Id.* at 22).

"Claim terms are given their ordinary and customary meaning—the meaning that they would have to a person of ordinary skill in the art in light of the specification and prosecution history at the time of the invention." *Woods*, 692 F.3d at 1283. And "[c]laim terms are properly

construed to include limitations not otherwise inherent in the term only when a patentee sets out a definition and acts as his own lexicographer, or when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Id.* (internal quotations omitted); *see also Thorner*, 669 F.3d at 1365 ("To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning. It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to redefine the term. . . . The standard for disavowal of claim scope is similarly exacting. . . . Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal. . . . It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that.").

The Court finds that the '895 patent does not provide lexicography or clear disavowal sufficient to incorporate movement limitations that are not otherwise inherent in the disputed claim language. It is not enough that the disclosed embodiments have the movement limitations at issue. *See Thorner*, 669 F.3d at 1365. And the Court is not convinced that the patentee provided implied lexicography because, as BD correctly observes, Insulet seems to rely on an "aspect of the invention" that is embodied in Claim 1, not Claim 14. (*Compare* '895 Patent at 2:23-53, *with* Claim 1 of the '895 Patent). Indeed, for purposes of construing this term, the portion of the specification that seems to correlate with Claim 14 does not provide explicit or implied lexicography requiring the movement limitations that Insulet now seeks to incorporate into the disputed claim language. (*See* '895 Patent at 2:54-3:8).

Conversely, the Court finds that BD's proposal comports with how an ordinary artisan would understand "adapted to communicate with said reservoir" in view of the specification. (*See id.*); *see also Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1349 (Fed. Cir. 2012) (citations omitted) ("In common parlance, the phrase 'adapted to' is frequently used to mean 'made to,' 'designed to,' or 'configured to,' but it can also be used in a broader sense to mean 'capable of' or 'suitable for.'"). The Court agrees with BD that the '895 patent discloses a variety of features that permit the injection needle to receive fluid from the reservoir. (*See, e.g.*, '895 Patent at 2:37-41 (disclosing that "a second portion extending generally parallel to the bottom surface of the housing for communicating with the reservoir"); 5:42-45 (explaining that the "rearwardly-facing end **63** of the injection needle **54**" aligns with the reservoir's port to communicate with the reservoir); 7:35-42 ("[T]he rearward movement of the needle carrier **52** causes the sharpened tip **63** at the proximal end of the injection needle **54** to penetrate a seal-sealing rubber septum **90** in the port **56** of the liquid reservoir **50**.")). The Court accordingly rejects Insulet's invitation to incorporate certain of these features into the disputed claim language absent lexicography and clear disavowal to that effect.[17]

4. "an injection needle having a bent injection end"

The parties dispute the meaning of this term again found in asserted Claim 14 of the '895 patent, which appears as follows (with bold typeface for the disputed claim language):

[17] The Court's refusal to read limitations into "adapted to communicate with said reservoir" is not inconsistent with the Court's finding certain limitations inherent in "injection needle" above. For the "adapted to communicate with said reservoir" language, the '895 patent discloses a variety of features that permit the injection needle to communicate with the reservoir, and the Court is not convinced that there is lexicography or disavowal to emphasize one of those features (i.e., the movement feature). For the "injection needle" language, however, the '895 patent emphasizes, as a fundamental feature, that the needle must be inserted into a patient for a therapeutic preparation or fluid to be delivered. *See SciMed Life Sys.*, 242 F.3d at 1342-44 (finding disclaimer of subject matter and construing claim language accordingly).

> 14. A device for delivering a liquid theraputic [sic] preparation into the body of a patient by injection into or through the skin, comprising:
>
> a low-profile housing having a bottom surface adapted to be brought into contact with the skin of a patient, said bottom surface having a needle aperture therein, said housing being sufficiently low in height to allow said device to be worn inconspicuously under the clothing of the patent [sic];
>
> a reservoir disposed within said housing for containing a liquid theraputic [sic] preparation;
>
> an injection needle disposed generally horizontally in said housing and adapted to communicate with said reservoir, said **injection needle having a bent injection end** adapted to project through said needle aperture; and
>
> a movable needle carrier disposed in said housing for carrying said injection needle and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier;
>
> wherein said needle carrier and said injection needle are disposed in a side-by-side relationship with said reservoir in said housing in order to minimize the height of said housing above said bottom surface.

BD's Proposed Construction: "An injection needle wherein the distal injection end is oriented in a different direction than its proximal end"

Insulet's Proposed Construction: "An injection needle, as defined above, that includes a permanent bend or deflection near the end of the needle that is inserted into the body of a patient. (Alternatively, near the downstream end of the needle.)"

Court's Construction: "An injection needle wherein the distal injection end is oriented in a different direction than its proximal end"

BD argues that its construction is consistent with the claim language and specification. (BD Open. Br. at 44 (citing '895 Patent at 2:35-41)). Relying on the patent's description of Figure 4, BD contends that the needle includes a main portion that extends parallel to the lower housing and that the forward end of the needle is bent at an angle of about 90 degrees relative to

the main portion. (*Id.* at 44-45 (citing '895 Patent at 6:9-14 & 6:21-23)). Thus, BD argues that its proposal comports with the description in the patent. (*Id.* at 45). And BD insists that Insulet's proposal, namely the "near" portions, adds limitations that do not exist in the claim language and unnecessarily complicates claim construction. (*See id.* at 45-46 (referencing "deflection *near* the end of the needle that is inserted into the body of a patient" and "*near* the downstream end of the needle" portions of Insulet's proposal) (emphasis added)). BD further contests that any part of the '895 patent describes a *hard* injection needle having a *permanent* bend. (BD Resp. Br. at 23).

Insulet explains that the parties' proposals differ in two ways. First, Insulet contends that its proposal places the bend in the injection needle near the end of the needle that is inserted in the patient, whereas BD's proposal permits the bend to be anywhere along the needle. (Insulet Resp. Br. at 22). Insulet argues that BD's proposal ignores the following disclosures: the plain words of the claim, which require a bend at the "injection end"; the written description, which states that the "forward end of" the needle is bent; and Figures 4-8, which depict a bend in an injection needle at the extreme forward end. (*Id.*).

Second, Insulet contends that its proposal defines the "bent injection end" as a *permanent* bend or deflection in the injection needle, whereas BD's does not. (*Id.* at 22-23). To this point, Insulet explains that the patent discloses an injection needle that has a permanent bend, preferably one that is made of stainless steel. (*Id.* at 23 (citing '895 Patent at 6:27)).

Insulet's proposal includes the two above-mentioned limitations that are not inherent in the disputed claim language. But these two limitations are not supported by lexicography or disavowal. First, Insulet maintains that the bend be *near* the end of the needle that is inserted into the body of a patient. (Insulet Resp. Br. at 22; *see also* Claim 14 of '895 Patent (describing

"injection needle having a bent injection end adapted to project through said needle aperture")). The Court agrees with BD, however, that the '895 patent describes that the distal injection end is oriented in a different direction than the proximal end, without requiring that the bend or deflection be "near" the needle end that is inserted into a patient. (*See* '895 Patent at 6:9-14 ("The injection needle **54** is secured to the bottom surface of the needle carrier **52** in a manner such that the main or unbent portion **72** of the injection needle **54** extends approximately parallel to the plane of the lower housing portion **24** and is aligned with the longitudinal center line of the device **20**"); 6:21-23 ("The forward or distal end **76** of the injection needle **54** is bent at an angle of about 90° relative to the main or proximal portion **72** of the injection needle . . . .")). The Court is not persuaded otherwise by Insulet's reliance on Figures 4-8, which purportedly depict a bend in an injection needle at the extreme forward end. *See Thorner*, 669 F.3d at 1365-66.

Second, the Court disagrees that the bend or deflection is necessarily "permanent." (*See* Claim 14 of '895 Patent (claiming "injection needle having a bent injection end adapted to project through said needle aperture")). At most, Insulet points to the patent's disclosure that the needle is preferably made of stainless steel. (Insulet Resp. Br. at 23 (citing '895 Patent at 6:27)). This is insufficient to amount to lexicography or disavowal. *See Thorner*, 669 F.3d at 1365. The Court therefore adopts BD's proposal.

5. "a needle carrier . . . for carrying said injection needle and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier"

The parties dispute the meaning of this term again from asserted Claim 14 of the '895 patent, which appears as follows (with bold typeface for the disputed claim language):

> 14. A device for delivering a liquid theraputic [sic] preparation into the body of a patient by injection into or through the skin, comprising:

> a low-profile housing having a bottom surface adapted to be brought into contact with the skin of a patient, said bottom surface having a needle aperture therein, said housing being sufficiently low in height to allow said device to be worn inconspicuously under the clothing of the patent [sic];
>
> a reservoir disposed within said housing for containing a liquid theraputic [sic] preparation;
>
> an injection needle disposed generally horizontally in said housing and adapted to communicate with said reservoir, said injection needle having a bent injection end adapted to project through said needle aperture; and
>
> **a** movable **needle carrier** disposed in said housing **for carrying said injection needle and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier**;
>
> wherein said needle carrier and said injection needle are disposed in a side-by-side relationship with said reservoir in said housing in order to minimize the height of said housing above said bottom surface.

BD's Proposed Construction: "A component for holding the injection needle and moving the needle horizontally into position for fluid delivery"

Insulet's Proposed Construction: "This is a means plus function claim limitation. The claimed functions are carrying an injection needle and causing the injection end of the injection needle to project through the needle aperture. The claimed means is needle carrier 52 and equivalents. Alternatively, a manually-actuated structure that holds an injection needle—alternatively, to which an injection needle is affixed—along substantially its entire horizontal portion and includes a resilient portion that is used to insert the needle into the body of the patient and a non-resilient portion that is used to insert the needle into a medication reservoir"

Court's Construction: "A component for holding the injection needle and moving the needle horizontally into position for fluid delivery"

As an initial matter, BD argues that, since the claim term "does not lack structure and does not use 'means,' . . . there is a strong presumption that § 112, ¶ 6, does not apply." (BD Open. Br. at 47). BD contends that this presumption is overcome "only if the claim term recites a function without reciting any structure whatsoever." (*Id.*). To that extent, BD argues that the

term "need only 'convey to one knowledgeable in the art a variety of structures' to which the term refers." (*Id.* (quoting *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998)). BD asserts that, here, the well-understood meaning of "carrier"—which has an "ordinary meaning as a noun denoting structure" in the context of "needle carrier"—belies Insulet's position. (*Id.* at 47-48 (citing general purpose dictionary definition as "[a] mechanism or device by which something is conveyed or conducted" at Ex. N to BD Open. Br.)). BD also argues that, even if the disputed term does not conjure up a *particular* structure, broad terms may nevertheless convey structure as long as they are not generic structural terms such as "means, element, or device." (*Id.* at 48 (quoting *Personalized Media Commc'ns*, 161 F.3d at 704)). And BD adds that "nothing in the intrinsic evidence shows that BD intended to invoke § 112, ¶ 6, when drafting the claims" and that the '895 patent "makes clear that BD used 'needle carrier' to denote structure." (*Id.*). Finally, BD avers that the specification uses "needle carrier" as a name for the structure shown in Figures 3 and 4 of the '895 patent. (*Id.* at 49).

As to Insulet's alternative proposals, BD argues that Claim 14 does not call for "(1) the 'needle carrier' to be a 'manually-actuated structure,' (2) the injection needle to be 'affixed' to the needle carrier 'along substantially its entire horizontal portion,' or (3) the 'needle carrier' to 'include a resilient portion that is used to insert the needle into the body of the patient.'" (*Id.*). BD asserts that Insulet improperly imports these narrow features from the specification, resulting in a confusing proposal. (*Id.* at 49-50). BD argues that its own proposal is consistent with the claim language and supported by the specification. (*Id.* at 50 (citing Claim 14 & the '895 Patent at 6:9-10; 7:15-33)).

Insulet argues that "[l]imitations that do not use the word 'means' are subject to a rebuttable presumption that Section 112, ¶ 6, does not apply." (Insulet Open. Br. at 47). Insulet

maintains that this presumption "may be rebutted by a demonstration that the claim limitation fails to 'recite sufficiently definite structure' or recites a 'function without reciting sufficient structure for performing that function.'" (*Id.* (quoting *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1319 (Fed. Cir. 2004)). Accordingly, Insulet contends that "needle carrier" is itself functional because it "encompasses anything that carries a needle" and that the rest of the claim limitation is a "further functional description." (*Id.*; *see also* Insulet Resp. Br. at 23 ("It is a structure whose function is to (a) carry an injection needle and (b) cause the injection end of the needle to project through the needle aperture of the device.")). Relying on an expert declaration, Insulet argues that the term "needle carrier" does not have an accepted or generally understood structural meaning to an ordinary artisan. (Insulet Open. Br. at 47). Indeed, Insulet contends that BD's proposal confirms this point because BD defines the term needle carrier "by reference to what a structure does, not what it is." (*Id.* at 48 (citing BD's proposal)).

Alternatively, Insulet argues that, even if a Section 112, ¶ 6 analysis does not apply, the '895 patent "defines the claim term by implication." (*Id.*). To that extent, Insulet argues that its proposal "is a definition that construes a structural component by reference to its actual structure" whereas "BD's proposed construction places no structural limitation of any kind on this claim." (*Id.* at 48-49 (citing '895 Patent at 2:3-6; 2:45-53; 4:36-49; 5:63-6:21; 6:45-47; 6:63-74; 7:25-33; 7:35-43; and Figures 4-6)).

a. Whether Section 112, ¶ 6 Applies

"When a claim term lacks the word 'means,' the presumption can be overcome if the challenger demonstrates that 'the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.'" *Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, 649 F.3d 1350, 1356 (Fed. Cir. 2011) (quoting *CCS*

Fitness v. Brunswick Corp., 288 F.3d 1359, 1369 (Fed. Cir. 2002)). "The presumption that a claim lacking the term 'means' recites sufficiently definite structure can be rebutted 'if the evidence intrinsic to the patent and any relevant extrinsic evidence so warrant[s].'" *Inventio AG*, 649 F.3d at 1356 (quoting *Personalized Media Commc'ns*, 161 F.3d at 704)). Thus, "[i]n cases where the claims do not recite the term 'means,' considering intrinsic and extrinsic evidence is usually helpful, as the litigated issue often reduces to whether skilled artisans, after reading the patent, would conclude that a claim limitation is so devoid of structure that the drafter constructively engaged in means-plus-function claiming." *Inventio AG*, 649 F.3d at 1357; *see also Power Integrations*, 711 F.3d at 1364 ("We assess whether a claim limitation recites sufficient structure to avoid means-plus-function claiming from the vantage point of an ordinarily skilled artisan."). To be sure, however, "the presumption flowing from the absence of the term 'means' is a strong one that is not readily overcome." *Inventio AG*, 649 F.3d at 1356.

Here, the limitation does not use the word "means" and therefore is presumed not to invoke Section 112, ¶ 6. *See id*. Accordingly, the Court must determine whether "needle carrier" is a generic structural term, such as "means," that does not provide any structure to the limitation-at-issue. *See Personalized Media Commc'ns*, 161 F.3d at 704. The Court therefore turns to the intrinsic and extrinsic evidence for guidance, but finds that the term "needle carrier" sufficiently recites structure.

First, Claim 14 describes the relationship of "needle carrier" to other claim terms and this provides clues about structure: "wherein said needle carrier and said injection needle are disposed in a side-by-side relationship with said reservoir in said housing in order to minimize the height of said housing above said bottom surface." *See Mass. Inst. of Tech. v. Abacus Software*, 462 F.3d 1344, 1356 (Fed. Cir. 2006) ("The claim language here . . . does not merely

describe a circuit; it adds further structure by describing the operation of the circuit."). Second, the specification uses the term "needle carrier" as the name for structure. (*See, e.g.*, '895 Patent at 6:50-7:4 ("When the needle carrier **52** is at its forwardmost position in the lower housing portion **24** . . . . Since the guide portion **68** at the rear of the needle carrier **52** is prevented from moving upwardly by the guide tracks **82**, the needle carrier **52** is thus maintained in a resiliently stressed condition . . . . This is the condition in which the needle carrier **52** exists prior to use of the automatic injection device **20**. When the device **20** is used, the needle carrier **52** is moved . . . . This allows the resiliently deflectable portion **70** of the needle carrier **52** to deflect downwardly . . . ."). Third, extrinsic evidence indicates that "carrier" has a dictionary definition—"[a] mechanism or device by which something is conveyed or conducted"—suggesting that the "disputed term has achieved recognition as a noun denoting structure, even if the noun is derived from the function performed." *See Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1360-61 (Fed. Cir. 2004) (finding that "[d]ictionary definitions in this case disclose that the term 'connector' has a reasonably well-understood meaning as a name for structure, even though the structure is defined in terms of the function it performs").

To be sure, the Court is not persuaded otherwise by Insulet's insistence that this term "does not describe or connote a *particular* structure." (*See* Insulet Open. Br. at 47 (emphasis added)). This is not dispositive. *See Lighting World*, 382 F.3d at 1360 ("[W]hile it is true that the term 'connector assembly' does not bring to mind a particular structure, that point is not dispositive. What is important is whether the term is one that is understood to describe structure, as opposed to a term that is simply a nonce word or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term 'means for.'"); *Personalized Media Commc'ns*, 161 F.3d at 705 ("Even though the term 'detector' does not specifically evoke a

particular structure, it does convey to one knowledgeable in the art a variety of structures known as 'detectors.'").

The Court is also not persuaded by Insulet's assertion that "'needle carrier' does not have an accepted or generally understood structural meaning to persons of ordinary skill in the art," based on Insulet's expert declaration. (*See* Insulet Open. Br. at 47). As discussed above, the '895 patent and a dictionary definition suggest that "in the context of the claimed invention, the function recited is sufficiently clear, and definitely described, to suggest to the ordinarily skilled artisan a defined class of structures." *See Power Integrations*, 711 F.3d at 1365. The Court therefore finds that "needle carrier" is not a generic structural term such as "means" that requires a Section 112, ¶ 6 analysis. Accordingly, the Court must now construe the disputed claim language using ordinary principles of claim construction.

b. Scope of disputed language

"Claim terms are given their ordinary and customary meaning—the meaning that they would have to a person of ordinary skill in the art in light of the specification and prosecution history at the time of the invention." *Woods*, 692 F.3d at 1283. The Court finds that BD's proposal—"a component for holding the injection needle and moving the needle horizontally into position for fluid delivery"—aligns with the claim language and the patent's description of the invention. Claim 14 provides, in relevant part, for "a movable needle carrier disposed in said housing for carrying said injection needle and for causing the injection end of said needle to project through said needle aperture upon movement of said needle carrier." Indeed, the specification explains that the "injection needle **54** is secured to the bottom surface of the needle carrier **52**." ('895 Patent at 6:9-10). Thus, the needle carrier holds the injection needle.

Additionally, Claim 14 and the specification suggest a component for moving the needle horizontally into position for fluid delivery. ('895 Patent at Claim 14 ("[A] movable needle carrier . . . ."); 2:49-53 ("[M]ovement of the needle carrier between the first and second positions causes the injection needle to penetrate the skin of the patient, and also causes the liquid theraputic [sic] preparation to begin to flow through the injection needle into the body of the patient."); 6:63-7:4 ("When the device **20** is used, the needle carrier **52** is moved (via the slide button **42**) in the direction toward the reservoir **50** . . . . This motion provides the injection force that causes the distal portion **76** of the injection needle **54** to penetrate the skin of the patient."); 7:35-43 ("[T]he rearward movement of the needle carrier **52** causes the sharpened tip **63** at the proximal end of the injection needle **54** to penetrate a self-sealing rubber septum **90** in the port **56** of the liquid reservoir **50**. The proximal end of the injection needle **54** thereby enters the liquid chamber within the reservoir **50** . . . and a flow path is established between the reservoir **50** and the body of the patient through the lumen of the injection needle **54**.").

Even accepting Insulet's argument that "needle carrier" does not have an accepted meaning in the relevant art, (*see* Insulet Resp. Br. at 23), the Court must still look to the specification for guidance. *See Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 991 (Fed. Cir. 2007) ("Without a customary meaning of a term within the art, the specification usually supplies the best context for deciphering claim meaning."); *Phillips*, 415 F.3d at 1315 ("[T]he specification . . . is the single best guide to the meaning of a disputed term.") (internal quotations omitted).

In effect, Insulet is asking the Court to redefine the disputed term based on the mere disclosure of certain features. (*See* Insulet Open. Br. at 48 ("In effect, the written description of the patent defines the claim term by implication.")). That is not enough. *See Thorner*, 669 F.3d

at 1365. Specifically, the specification does not sufficiently define the disputed claim language to include the limitations in Insulet's proposal—i.e., that a needle carrier is "(a) a manually-actuated structure . . . that (b) holds or is affixed to an injection needle along substantially the entire length of the needle . . . (c) includes a resilient portion that is used to insert the needle into the body of the patient . . . and (d) a non-resilient portion that is used to insert the needle into a medication reservoir." (*See* Insulet Open. Br. at 48-49). In sum, the Court refuses to narrow the scope of the disputed term because neither the specification nor the prosecution history of the '895 patent provides lexicography or clear expressions of restriction or disavowal, as Insulet proposes.[18]

II. Conclusion

For the reasons set forth above, the Court construes the disputed claim terms as indicated. An appropriate Order accompanies this Opinion.

/s/ Esther Salas
Esther Salas, U.S.D.J.

[18] BD's proposal for "a needle aperture" from Claim 14 of the '895 patent is undisputed. (*See generally* Insulet Open. Br. & Insulet Resp. Br.; *see also* BD Resp. Br. at 17 ("BD's construction of 'a needle aperture' is undisputed.")). Therefore, the Court adopts BD's proposal for this term. And, for the same reasons discussed in Section IV, Part B *supra*, the Court defers resolving Insulet's indefiniteness challenge concerning the term "housing being sufficiently low in height to allow said device to be worn inconspicuously under the clothing of the patent [sic]" from Claim 14 of the '895 patent. (*See* Insulet Open. Br. at 49).